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CHAPTER II

Preliminary Classification: Proposed Class: A61K

Subclass:

9/00

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

04 November 2003

PCT/EP03/012272

(04.11.03)

13 November 2002 (13.11.02)

International Application No.

International Filing Date

Priority Date Claimed

Multi-Layer Transmucosal Therapeutic System

Title of Invention

Krumme, Markus

Applicant(s)

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

EXPRESS MAILING UNDER 37 C.F.R. § 1.10*

(Express Mail label number is mandatory.) (Express Mail certification is optional)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date MAY 4, 2005 in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 as "Express Mail Post Office to Addressee" Mailing Label No. EV203146098US.

Christine Kotran

Date: May 4, 2005

Type or print name of person mailing paper

Signature of person certifying

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Transmittal Letter to the United States Elected Office (EO/US)--page 1 of 4

^{*}WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

[&]quot;Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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- 1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:
 - a. This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).
 - b. The U.S. Basic National Fee (35 U.S.C. § 371(a)):

| NATIONAL STAGE Examination fee | | | | | | | |
|------------------------------------|--|---------------------|---|----------|------------|--------------|--|
| FEES* | Examination fee \$200.00 | | | | | \$ | |
| | Search fee \$500.00 | | | | | | |
| CLAIMS FEE* (1) FOR | (2) NUMBER FILED | (3) NUMBER EXTRA | | (4) RATE | | \$ | |
| TOTAL CLAIMS | 22 - 20 = | 2 | x | \$ | 50.00 = | \$100.00 | |
| INDEPENDENT CLAIMS | 2 - 3 = | | x | \$ | 200.00 = | \$0.00 | |
| MULTIPLE DEP (if applicable) | MULTIPLE DEPENDENT CLAIM(S) + \$ 360.00 | | | | | \$0.00 | |
| Basic filing fee* \$3 | Basic filing fee* \$300.00 \$300.00 | | | | | | |
| Examination fee | Examination fee | | | | | \$200.00 | |
| All other situati | All other situations \$200.00 | | | | | \$200.00 | |
| Search fee \$500.0 | 0 | | | | | | |
| International So | International Search Report prepared and provided to the Office \$400.00 | | | | | \$400.00 | |
| ADDITIONAL (excluding sequence | medium). The fee is \$250.00 for each additional 50 sheets of paper or | | | | | | |
| Total Sheets: Ext | Extra Sheets: () | | | | | \$0.00 | |
| | -+Total of above Calculations | | | | | = \$1,000.00 | |
| | | | | | | - \$0.00 | |
| Subtotal Total National Fee | | | | | \$1,000.00 | | |
| | | | | | \$1,000.00 | | |
| | Fee for recording the enclosed assignment document \$40.00 (37 C.F.R. § 1.21(h)). See Item 13 below). See attached "ASSIGNMENT COVER SHEET". | | | | | \$0.00 | |
| TOTAL | Total Fees enclosed | | | | | \$1,000.00 | |

2. A copy of the International application as filed (35 U.S.C. § 371(c)(2)) is transmitted herewith.

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- 3. A translation of the International application into the English language (35 U.S.C. § 371(c)(2)) is transmitted herewith.
- 4. Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)) are not transmitted herewith.
- 5. A copy of the international examination report (PCT/IPEA/409) is transmitted herewith
- 6. Annex(es) to the international preliminary examination report are transmitted herewith.
- 7. A translation of the annexes to the international preliminary examination report is transmitted herewith.
- 8. An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115 will follow.
- **II.** Other document(s) or information included:
- 9. An International Search Report (PCT/ISA/210) is transmitted herewith.
- 10. An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98 is transmitted herewith.

 Also transmitted herewith is Form PTO-1449 (PTO/SB/08A and 08B).
- 11. Additional documents:
 - a. International Publication No. WO04043426
 - i. Front page only
 - b. First Written Opinion dated April 20, 2004 and response to First Written Opinion dated August 20, 2004
 - c. Second Written Opinion dated December 16, 2004 and response to Second Written Opinion dated June 15, 2005 (sic).
 - d. Return postcard receipt
 - e. Preliminary amendment with clean and marked-up substitute specifications
 - f. Credit card payment form
- 12. The above items are being transmitted before 30 months from any claimed priority date.

AUTHORIZATION TO CHARGE ADDITIONAL FEES AND CREDIT OVERPAYMENTS

Please charge any additional fees and credit any overpayments to Deposit Account No. 08-2441 in the name of D. Peter Hochberg Co., L.P.A.



10/533835

AS REC'UPCTIPTO 04 MAY 2005

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